

MAY 25 2004



K040881

## Great Lakes Orthodontics, LTD.

*An Employee Owned Company*

*Our Vision*

*"Delight our customers. Respect and help our co-workers."*

### 510(k) SUMMARY

CONTACT PERSON: Mr. Mark Lauren      Great Lakes Orthodontics 800-828-7626  
[mlauren@greatlakesortho.com](mailto:mlauren@greatlakesortho.com)

DATE PREPARED: April 2, 2004

TRADE OR PROPRIETARY NAME: Metacryl

COMMON NAME: Dental acrylic, soft denture reline

CLASSIFICATION NAME: Denture relining, repairing or rebasing resin 872.3760

PRODUCT CODE: EBI

PREDICATE DEVICE: Flexacryl Soft      Lang Dental Corporation  
175 Messner Drive  
Wheeling, IL 60090      800-222-5264

#### DEVICE DESCRIPTION

Metacryl is a chemically cured soft denture reline. All components have been used in legally marketed devices or have been found to be safe for dental use.

#### INTENDED USE

Metacryl is intended for the chairside fabrication of soft denture reline.

#### TECHNOLOGICAL CHARACTERISTICS COMPARED WITH PREDICATE DEVICE

Metacryl was evaluated as follows:

Mechanical properties, Hardness, Water absorption, Discoloration, Peel strength

Metacryl was also evaluated as follows:

ISO Agar Overlay Cytotoxicity Test      non-cytotoxic

We conclude that the similarity in composition between Metacryl and the predicate device, as well as the performance data and biocompatibility results, supports the safety and effectiveness of Metacryl for the indicated uses.

200 Cooper Avenue • P.O. Box 5111 • Tonawanda, New York 14151-5111  
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 25 2004

Mr. Mark Lauren  
Great Lakes Orthodontics, Limited  
200 Cooper Avenue  
P.O. Box 5111  
Tonawanda, New York 14151-5111

Re: K040881  
Trade/Device Name: Metacryl™ Soft Denture Reline  
Regulation Number: 872.3760  
Regulation Name: Denture Relining Repairing or Rebasing Resin  
Regulatory Class: II  
Product Code: EBI  
Dated: April 2, 2004  
Received: April 6, 2004

Dear Mr. Lauren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K040881

Great Lakes Orthodontics  
200 Cooper Avenue  
Tonawanda, NY 14150

**Device Name:** Metacryl™ soft denture reline

### Indications for Use:

Metacryl™ is intended for the chairside fabrication of soft relines for dentures.

Prescription Use ☒  
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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